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INTRODUCTION

In-home tele-behavioral health treatments have the potential to address current health needs of Service Members, Veterans, and their families, especially for those that live in rural and underserved areas. The use of in-home web-based treatment to address the psychological needs of Service Members and Veterans is not yet considered standard of care for the DoD. The safety and clinical efficacy of such treatments must be established before broad dissemination of these treatment programs. This study is a two-group (web-based in-home BA vs. in-person BA) prospective randomized controlled trial. Both groups will be assessed at baseline, mid-treatment (Week 4), post-treatment (Week 8), and at a 3-month follow-up visit. The primary outcome variables are safety and hopelessness. Secondary outcome variables include depression, anxiety, PTSD symptoms, attitudes toward seeking mental health services, quality of life, and health care utilization, as well as treatment satisfaction, adherence, and compliance. A total of 120 participants will be recruited with an anticipated completion rate of 108 participants (54 per treatment group). Participants are Regular Service Members, National Guard Members, Reservists, and Veterans recruited at Madigan Army Medical Center and the Portland VA Medical Center.

BODY

The protocol was submitted to the Madigan Healthcare System Institutional Review Board (IRB) on 05 April 2011. The IRB granted conditional approval of the research protocol on 25 October 2011. Revisions were made base on those recommendations and submitted to the IRB on 07 November 2011 and the protocol was approved 21 November 2011. The protocol was reviewed by The Human Research Protection Office (HRPO) on 24 February 2012. Revisions were requested by HRPO at that time, the PI and Co-PI have attempted to reach HRPO to discuss revisions without success. The Department of Veterans Affairs (VA) IRB Portland approved the protocol on 08 November 2011. The Portland VA site does not have HRPO approval as of the time of this report.

The pilot study protocol was submitted to the Madigan Healthcare System Institutional Review board on 15 July 2011. The IRB granted approval of the research protocol on 14 February 2012. This protocol had been on the IRB meeting agenda for November, and January was not deferred both times due the IRB either not having quorum or not enough time to complete review of items on the agenda. HRPO approval of this protocol is still pending.

A research coordinator was hired for the T2/JBLM site at 10% effort, completed training and a research coordinator was added to this grant at 50% effort and completed training. The clinical psychologist hired at T2/JBLM, was terminated based on performance related issues. Recruitment, interviewing and hiring is continuing at T2 for the outcomes assessor and clinical psychologist positions. An offer was extended and accepted for the outcomes assessor position at the Portland VA. The start date for the outcomes assessor will be March 26, 2012. Recruitment, interviewing and hiring is continuing at the Portland VA for the research coordinator position.

Challenges

IRB and HRPO approval continues to be a challenge due to delays in the review/approval process.

KEY RESEARCH ACCOMPLISHMENTS

Administrative and Logistical Matters

1. Personnel
 - a. Recruitment, interviewing and hiring a research coordinator and clinical psychologist at Madigan and was completed. Termination of the T2 clinical psychologist. Recruitment, interviewing and hiring for the clinical psychologist and outcomes assessor continues. An offer was extended and accepted for the outcomes assessor position for the Portland VA. The start date is 26 March 2012. Recruitment, interviewing and hiring a research coordinator at Portland VA continues.
2. Equipment
 - a. Ordered and received 10 laptops for the Portland site. All laptops have been configured according to the specifications required for the protocol. Acquired 10 webcams and all required accounts from USAMITC for MOVI (now Jabber video). All equipment has been tested within the Madigan network and outside the network.
3. Materials, supplies and consumables
 - a. Materials and required supplies, including study measures have been acquired in anticipation for subject enrollment and data collection.
4. Institutional Review Board (IRB)
 - a. Madigan IRB approved on 21 November 2011.
 - b. Madigan IRB approval of the pilot study 14 February 2012.

REPORTABLE OUTCOMES

None

CONCLUSION

None

REFERENCES

None

APPENDICIES

None